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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,560	12/28/2000	Jaan Noolandi	XER 2 0399	6443

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/17/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,560

Applicant(s)

NOOLANDI ET AL.

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 13, 16 and 20-26 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12, 14, 15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The office would like to thank Mr. Mr. Dreher for the telephone discussion on 5/27/03 in which the office raised the concern over the term "single scan pass". Upon further review the term still would cover Nasu et al teachings in that, within a single scan pass Nasu takes a full image on the gel apparatus. The office welcomes an interview to further discuss the cited prior art and claims.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 17-19 recite the illumination means and depend on claim 14 but claim 14 does not recite an illumination means. Antecedent basis is lacking.

No changes to claims or response has been made to obviate the rejection. The rejection is therefore maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 9, 12, 14,15,17,18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nasu et al (US5,246,866 September 21, 1993).

Nasu et la teach a DNA sequencing apparatus in which fluorescently labeled fragments are subject to electrophoresis and illuminated and exposed to detection to create an image corresponding to gel (see whole doc. esp. abstract). They teach the apparatus (see Figure 7) with an electrophoresis unit 73 (separation apparatus) with an upper electrode 74a and lower electrode 74b, which applies an electric field to separate fragments and optical sensor 78 (detector) and optical source 71 (illumination means) (see col.. The apparatus contains a gel which is a polymer solution. The apparatus is attached to processing unit which can create image corresponding to gel(see Figure 5-7). The light receiving elements are arranged perpendicular to the direction of electrophoresis (see col 4 line 5). The image represents the same type of the gel (see col. 4 lines 31-37 & figure 2). The detector scans the full width of the array of samples in gel (see figure 7). Detection occurs over several time periods(see col. 7 line 59).

The response filed 4/15/03 has been fully considered and deemed not persuasive. The response states that Nasu describes constantly scanning in the direction of migration using

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multiple scans. While Nasu et al do use multiple scans, within a single scan the full image of the gel is processed. It is only with multiple transmission of the light to film that is repeated, the photoelectric detector still functions within a single scan pass (see in particular col. 6 lines 15-26). The term in a "single scan pass" reads broadly and would encompass the detector in Nasu et al's device.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4,6,8-10,12,14,15 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al (US5,274,240 Dec, 28, 1993) in view of Birnbaum et al (US5,627,643 May 6, 1997).

Mathies et al teach the capillary gel electrophoresis for DNA sequencing (see whole document & col. 6 line 6 & col. 6 line 61).

Mathies et al do not full scan imaging.

Birnbaum et al teach a capillary electrophoresis apparatus to separate fluorescence (see whole doc. esp abstract). They teach an electrophoretic separation using an electric field (separation device) (see col. 1 line 26). They teach thin capillaries (see col. 1 line 29). In Figure 1

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they teach a laser which irradiates samples along the capillary (see col.2 line 20). They teach a CCD detector for generating an electronic image of the appearance of the capillary (see col. 2 lines 24-26 & figure 1). The detection is along the direction of migration (col. 3 line 32). They detect over various time intervals (see col.2 line 22).

One of ordinary skill in the art would have been motivated to apply Birnbaum et al's detection device to in order to provide real time detection of the various labels simultaneously. Birnbaum state that that the whole capillary may be examined momentarily allowing for simultaneous detection which provides a quicker evaluation (see col. 1 lines 40-65). It would have been prima facie obvious to apply Birnbaum et al's device to detect in capillary electrophoretic device in order to detect simultaneously and in real time the separation of DNA fragments.

The response states that the 103 rejections based on the combination Mathies and Birbaum et al should not be maintained because there is no suggestion to combine. Both Bernbaum and mathies et al teach the use of capillary electrophoresis. The use of CCD detector would be well within one of ordinary skill in the art to apply to Mathies in order to perform multiple sample detections. The rejections are therefore maintained.

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5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al (US5,274,240 Dec, 28, 1993) in view of Birnbaum et al (US5,627,643 May 6, 1997) in further view of Della Ciana et al (US6,136,612 Oct 24, 2000).

The teachings and suggestions of Mathies et al and Birnbaum et al are described previously.

Mathies et al do not full LED.

Della Ciana et al teach LED for fluorescent illumination in DNA sequencing (see col. 1 line10-11).

One of ordinary skill in the art would have been motivated to apply LED Mathies et al's apparatus in order to illuminate the fluorescent labeled fragments. Della Ciana et al state that LED's are cheaper, it would have been prima facie obvious to apply LEDs in order to provide for cost efficient light source.

6. Claims 5 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nasu et al (US5,246,866 September 21, 1993) in view of Frnakel et al

Nasu et al teach a DNA sequencing apparatus in which fluorescently labeled fragments are subject to electrophoresis and illuminated and exposed to detection to create an image corresponding to gel (see whole doc. esp. abstract). They teach the apparatus (see Figure 7) with an electrophoresis unit 73 (separation apparatus) with an upper electrode 74a and lower electrode 74b, which applies an electric field to separate fragments and optical sensor 78 (detector) and optical source 71 (illumination means) (see col.. The apparatus contains a gel which is a polymer solution. The apparatus is attached to processing unit which can create image corresponding to

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gel(see Figure 5-7). The light receiving elements are arranged perpendicular to the direction of electrophoresis (see col 4 line 5). The image represents the same type of the gel (see col. 4 lines 31-37 & figure 2). The detector scans the full width of the array of samples in gel (see figure 7). Detection occurs over several time periods(see col. 7 line 59).

Nasu et al do not teach lithographically etched channels.

Frankel et al teach lithographically etched channels in glass substrates(see col. 3 line 63-65).

One of ordinary skill in the art would have been motivated to apply Frankel et al's lithographically etched channels in glass substrates to Nasu et al's device in order to perform rapid and plurality separations. Frankel et al teach that channels provide for increased number of separations. It would have been prima facie obvious to apply Frankel's etched channels to Nasu et al's device in order to increase the number of samples that would be assayed during a single run.

THE FOLLOWING IS A NEW GROUND OF REJECTION

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,6,8,9,11,12,14,15,17 &18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mackay (US4,874,492 oct. 17, 1989).

Mackay et al teach a method of imaging bands of DNA using a charge couple device.
.they separate bands using electrophoresis apparatus and use light sensitive CCDs to create a
electronic representation of two dimensional full image (see whole doc. esp. col. 2 lines 46-64).

SUMMARY

8. Claims 7,13,16 and 20-26 are allowable. There is no prior art that teach or suggest the claimed method or device with amorphous silicon 2 dimensional image sensor array . There is no prior art that teach or suggest the claimed device where the laser is attached to the rear of the detector.

CONCLUSION

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.


JEFFREY SIEW
PRIMARY EXAMINER

June 1, 2003